



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,121	01/16/2004	Steven P. Gygi	58056 (70207)	7370
21874	7590	11/05/2007		
EDWARDS ANGELL PALMER & DODGE LLP			EXAMINER	
P.O. BOX 55874			HAQ, SHAFIQU	
BOSTON, MA 02205				
			ART UNIT	PAPER NUMBER
			1641	
			MAIL DATE	DELIVERY MODE
			11/05/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/760,121	<b>Applicant(s)</b> GYGI ET AL.	
	<b>Examiner</b> Shafiqul Haq	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4,6-9 and 11-45 is/are pending in the application.
- 4a) Of the above claim(s) 16-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,3,4,6-9 and 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Claims 1, 3, 4, 6-9 and 11-45 are pending of which claims 16-45 are withdrawn from further consideration as being directed to a non-elected invention (see office action of 2/8/07. See 37 CFR 1.142(b) and MPEP § 821.03. Because applicants did not traverse Examiner's response on restriction/e/election sent of 2/8/07, the election requirement is still deemed proper and is therefore made FINAL.
2. Claims 1, 3, 4, 6-9 and 11-15 are under active prosecution.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3, 4, 6-9 and 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 1, 3 and 6 recite "an isotope label". It is unclear what isotopes are intended to include by the term "an isotope label". Is the term "isotope label" also includes normal isotopes (e.g. C<sup>12</sup>). The term "isotope label" does not differentiate normally found isotopes (e.g. C<sup>12</sup>) from higher proportion of isotopes (e.g. C<sup>13</sup>). As for example, two samples can be labeled with two isotopes i.e. one having normal isotope (e.g. C<sup>12</sup>) and one having higher isotope (e.g. C<sup>13</sup>) for mass spectrometric analysis. Therefore, the term "isotope" label is not clear as to what isotopes are intended to include in this claim.

6. With respect to claim 1 and 4, different components of the tag molecule are vague and indefinite. Claim 1 recites "a tag molecule for mass spectrometric analysis of proteins, wherein the tag molecule comprises a reactive site for stably associating with a protein, an isotope label and a disulfide bond for covalently anchoring the tag molecule to a solid phase". The above recitation indicates that the tag molecule could be comprised only of a reactive site (e.g. COOH) wherein the reactive site is isotopically label (i.e. C<sup>13</sup>) and a disulfide bond (i.e. -S-S- group). Claim 4 recites, "tag molecule comprises an alkyl group, aryl group, heteroaryl group, arylalkyl group, heteroarylalkyl group or a cyclic molecule". It is not clear what component (s) of the tag molecule in claim 1 is represented by the recitation of claim 4 because "alkyl group, aryl group, heteroaryl group, arylalkyl group, heteroarylalkyl group or a cyclic molecule" do not represent a "reactive site", "an isotope label" or a "disulfide bond".

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1, 3, 4, 6-9 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter). The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "wherein the tag molecule comprises a reactive site for stably associating with a

Art Unit: 1641

protein, an isotope label and a disulfide bond for covalently anchoring the tag molecule to a solid phase" implies that the "disulfide" bond is a part of the tag molecule i.e. the tag molecules comprises three components 1) a reactive site 2) an isotope label and 3) a disulfide bond. This is (i.e. disulfide bond a part of the tag molecule) however, not supported in the specification. Page 13, lines 7-10 of the specification states

"In one aspect, a tag is associated indirectly with a solid phase through a through a linker molecule. As used herein, a "linker" refers to a bifunctional chemical moiety which comprises an end for stably associating with a solid phase and an end for stably associating with the tag. In one preferred aspect, the linker is cleavable".

Lines 17-20, of page 13, further states

"Preferably, the linker does not interact with the tag molecule except at the tag molecule's anchoring site and does not interact with the support except at the end of the linker which forms stable associations with the support".

Line 1 of page 14 further states:

"**Cleavable linkers also include those having disulfide bonds, ----**"

The above recitations clearly indicate that the "linker" (i.e. disulfide bond linker) is a not a part of the tag molecule but can be associated with a tag molecule for linking the tag molecule to a solid phase. Therefore, as disclosed in the specification, the "disulfide bond" as claimed in claim 1 is not a component or a part of the "tag molecule" and therefore, is not supported in the specification.

### ***Response to Argument***

3. Applicant's arguments filed 8/8/07 have been fully considered and are persuasive to overcome the rejections under 35 USC 102 and 35 USC 103 and some of the

rejections under 35 USC 112. However, Applicants' amendment necessitated new grounds of rejections (new matter), which are described in this office action.

With regard to the term "isotope label" in claims 1, 3 and 6, which do not differentiate normally found isotopes (e.g. C<sup>12</sup>) from higher proportion of isotopes (e.g. C<sup>13</sup>), instead of specifically pointing out which isotopes are included in the isotope label, Applicants states "Applicants have amended the claims to consistently use the term isotope label". This is not found convincing because two samples can be labeled with two isotopes i.e. one having normal isotope (e.g. C<sup>12</sup>) and one having higher isotope (e.g. C<sup>13</sup>) for mass spectrometric analysis. Therefore, the term "isotope" label is not clear as to what isotopes are intended to include in this claim.

With regard to withdrawn rejections under 35 USC 102 and 35 USC 103, applicants is advised that the rejections would be **reinstated** if tag molecule comprising a "disulfide bond" was removed from claim 1.

### ***Conclusion***

7. Applicants' amendment necessitated new ground(s) of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicant should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (e.g., if the amendment is not supported *in ipsius verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
SHAFIQUL HAQ  
EXAMINER  
ART UNIT 1641

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
ART UNIT 1641